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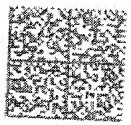

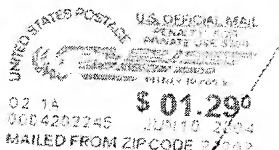

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,425	11/15/2000	Leonard Presta	P1726R1P1	3384

7590 06/10/2004

Wendy M Lee
1 DNA Way
South San Francisco, CA 94080-4990

EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
713,425	PRESTA
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 3/29/04.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 60-63, 80-82 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 60-63, 80-82 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

The amendment received 3/29/04 has been entered. Claims 60-63 and 80-82 are pending and under examination.

The disclosure is objected to because of the following informalities: at page 1, line 10 the current status of application 09/483, 588 must be indicated.

Appropriate correction is required.

The amendment has overcome 112 and obviousness type double patenting rejections of record.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

While applicant has disclosed that noncovalent complexes of the variant polypeptide and the Fc. gama. R allotypic receptor would occur in vivo, upon administration of the variant polypeptide to a subject, and while applicant has formed such noncovalent complexes in examples directed to evaluating the binding affinity of the polypeptide for the receptor, applicant has disclosed no utility for such noncovalent complexes. These are only a transiently existing complex formed in vivo, after administration of the variant polypeptides of the invention to a subject. These complexes cannot be provided in a vial and then administered to a patent. What would one do with such complexes? There is no well-established utility for these; indeed, it is conventional in the art for one to draw patent claims to a new drug but not to draw

claims to a new drug complexed with what would be its in vivo receptor, or other site of action (e.g. an enzyme). For example it is not well-established for one to claim a composition of a new beta one blocker and the beta one receptor. For one to claim an old drug complexed with its in vivo receptor, might overcome art but does not establish patentable subject matter.

Claims 60-63 and 80-82 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Prior art rejections are maintained as follows:

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 102(b) or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Indusogie et al (WO 99/51642 or US 6,242, 195).

See further below.

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Idusogie et al (6,528,624).

The Idusogie et al references were previously cited (action of 5/5/03) for teaching mutant/variant forms of IgGI which inherently have the property of increased binding affinity for an Fc. gamma. R allotype.--e.g. the K334A mutant having increased binding affinity for the Fc. gamma. RIIIA-V158 receptor. Applicant considers that the amended and new claims distinguish over the references, because none of these teach anything about binding to Fc. gamma. R allotypes.

It must, however, also be noted that applicant has urged (amendment at page 4) that the complex may occur with in vivo use, as taught at specification page 60, lines 1 and 4; also, it must be noted that Idusogie et al teach in vivo use throughout their disclosures. Therefore, it would have been inherent that the instantly claimed complexes would have been formed when IgGI antibodies having the taught mutant forms were administered to patients having allotypic Fc. gamma. R receptors (which are present, by nature, in a portion of any patient population); as far as the examiner can determine from the disclosures of Idusogie et al and applicant; there is nothing different about the formulations, dosages, and routes/schedules of administration that would not have inherently resulted in binding of the IgGI antibodies of Idusogie et al to such allotypic receptors.

The rejection has been alternatively stated under obviousness. In the event that any exemplified patients or contemplated patients of Idusogie et al did not have allotypic Fc. gamma. R receptors, it is taken as obvious that, with a large enough pool of patients, there would be those who, by nature, possessed allotypic Fc receptors.

Applicant's arguments filed 3/29/04 have been fully considered but they are not persuasive for the above reasons.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

Saunders/tgd

June 9, 2004

Applicant's Copy

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.	Serial No.
P1726R1P1	09/713,425
Applicant: Presta, L.	
Filing Date: 16 Nov 2000	Group: 1654

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
DAG	1	4,752,601	21.06.88	Hahn			
	2	5,348,876	20.09.94	Michaelsen et al.			
	3	5,624,821	29.04.97	Winter et al.			
	4	5,648,260	15.07.97	Winter et al.			
	5	5,698,449	16.12.97	Baumann et al.			
	6	5,736,137	07.04.98	Anderson et al.			
	7	5,935,599	16.11.99	McKenzie et al.			
	8	6,194,551 B1	27.02.01	Idusogie et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
DAG	9	WO 00/09560	24.02.00	PCT				
	10	WO 88/07089	22.09.88	PCT				
	11	WO 94/29351	22.12.94	PCT				
	12	WO 97/28267	07.08.97	PCT				
	13	WO 97/44362	27.11.97	PCT				
	14	WO 98/23289	04.06.98	PCT				
	15	WO 98/52975	26.11.98	PCT				
	16	WO 99/43713	02.09.99	PCT				
	17	WO 99/51642	14.10.99	PCT				
	18	WO 99/58572	18.11.99	PCT				

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Examiner: David A Saunders

Date Considered: 6/7/04

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Dept. of Commerce Patent and Trademark Office

Atty Docket No.	Serial No.
P1726R1P1	09/713,225
Applicant: Presta, L.	
Filing Date: 15 Nov 2000	Group: 1655

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Examiner	Date Considered
David A Saucier	6/7/04

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Atty Docket No.	Serial No.
P1726R1P1	09/71[illegible]5
Applicant: Presta, L.	
Filing Date: 15 Nov 2000	Group: 1653

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Examiner: David A Saucedo — Date Considered: 6/7/04

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Atty Docket No.	Serial No.
P1726R1P1	09/713,445
Applicant: Presta, L.	
Filing Date: 15 Nov 2000	Group: 1600

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Examiner: David A Saunders

Date Considered: 6/7/04

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U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.	Serial No.
P1726R1P1	09/714,425
Applicant: Presta, L.	
Filing Date: 15 Nov 2000	Group: 1651

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Applicant	
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